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No. 03-862

IN THE

Supreme Court of the United States

EXCEL CORPORATION,
Petitioner,

v.

ESTATE OF BRIANNA L. KRIEFALL, *ET AL.*,
Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether this Court has jurisdiction under 28 U.S.C. § 1257(a) to review a decision of a state court when reversal on the federal issue would not benefit petitioner and when other substantial issues would nonetheless remain to be resolved in further state-court proceedings.

2. Whether the state court of appeals was required to defer to a policy statement by the United States Department of Agriculture when the policy statement was inconsistent with the terms and purposes of the Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, and with other pronouncements and directives of the Agency itself.

RULE 29.6 STATEMENT

Respondent Sizzler USA Franchise, Inc. is a wholly owned subsidiary of Sizzler USA, Inc., which is a wholly owned subsidiary of Worldwide Restaurant Concepts, Inc., a publicly held company.

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BRIEF FOR RESPONDENTS IN OPPOSITION

STATEMENT

This case arises out of several consolidated state-law tort suits involving persons who became ill—and, in one case, died—after consuming food contaminated with the pathogen E. coli O157:H7. The source of the contamination was meat processed at a plant operated by petitioner Excel Corporation.

A. Federal Meat Inspection And The USDA Treatment of E. coli O157:H7.

The E. coli O157:H7 bacterium is a highly dangerous source of foodborne illness. "Exposure to E. coli O157:H7 has been linked with serious, life-threatening human illnesses (hemorrhagic colitis and hemolytic uremic syndrome)." 64

Fed. Reg. 2803 (Jan. 19, 1999). Moreover, unlike many other microorganisms, E. coli O157:H7 constitutes a serious threat to public health even at relatively low levels. As the Department of Agriculture (USDA) has said, "[s]ome pathogens, such as E. coli O157:H7, are so virulent that a small number of organisms can pose a significant hazard." 61 Fed Reg. 38,806, 38,835 (July 25, 1996).[1] For that reason, "any amount of E. coli O157:H7 will adulterate a meat or poultry product." *Id.*

E. coli O157:H7 is not naturally present in beef meat. Rather, E. coli O157:H7 is found in cattle feces and ingesta, and then transferred to meat through "fecal contamination." 61 Fed. Reg. 38,837. Fecal contamination, in turn, results from improper handling of carcasses during the slaughtering process. *See id.* ("without care being taken in handling and dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans"). The USDA has stated that "[i]n slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens." *Id.*

The virulent E. coli O157:H7 strain of E. coli was first discovered in 1982. Thus, while the Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et. seq.*, has long given the Agency authority to prevent distribution of "adulterated" meat products, *see* 21 U.S.C. § 606, the USDA for years did not identify E. coli O157:H7 as an adulterant.[2] That view

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[1] The USDA exercises many of its responsibilities regarding meat safety through the Food Safety and Inspection Service (FSIS). For simplicity, we generally use the terms "USDA" or "Agency" to refer to actions and declarations by the FSIS in the exercise of its delegated authority.

[2] The term "adulterated" is defined at 21 U.S.C. § 601(m). *See* Pet. App. 55a. Thus, a meat product is considered to be "adulterated" if, for example, "it bears or contains any poisonous or deleterious substance

changed in the early 1990s, however, following serious outbreaks of illness induced by E. coli O157:H7. The USDA subsequently adopted a policy that seeks to eradicate E. coli O157:H7 from meat and poultry products, with a current goal of reducing E. coli O157:H7 "to an undetectable level." *See* 67 Fed. Reg. 62,325, 62,329 (Oct. 7, 2002).

To achieve that goal, the Agency has enacted new rules requiring meat processing facilities to adopt Hazard Analysis and Critical Control Point (HACCP) plans that, among other things, prevent "contamination with fecal material and other intestinal contents . . . ." 61 Fed. Reg. 38,838. It thus has stated that "preventing and removing fecal contamination and associated bacteria are vital responsibilities of slaughter establishments." 61 Fed. Reg. 38,837. Recognizing that fecal contamination is "largely preventable," *id.*, the Agency requires slaughter establishments to adhere "to zero tolerance for fecal contamination." 61 Fed. Reg. 38,850.

The HACCP system altered USDA's prior program of organoleptic meat and poultry inspection by federal inspectors. Under the pre-HACCP program, every stage of meat production was monitored by USDA employees rather than by in-plant personnel. *See* Pet. App. 21a; USDA. Rep. No. 24001-3-At, at 1 (2000). The HACCP system reversed this arrangement by allowing—indeed requiring—a plant to monitor itself. As a result, the new HACCP rules "gave [the meat] industry, not Government, the primary responsibility for ensuring the safety of meat . . . products." *Id.*

The USDA has also recognized that "[o]ccurence of food-borne disease is a multi-step process." 61 Fed Reg. 38,966. In addressing the problem of dangerous pathogens, therefore,

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which may render it injurious to health" (with an exception for harmless amounts), 21 U.S.C. § 601(m)(1), or if it has been prepared "under insanitary conditions . . . whereby it may have been rendered injurious to health." 21 U.S.C. § 601(m)(4).

it has emphasized in the new HACCP rules that "[t]he first, and critical, step is the introduction of a pathogen into or onto the raw product." *Id.* Once E. coli O157:H7 has contaminated a meat product, it follows that any resulting illness has its roots in the initial flawed treatment. As the USDA has declared, "disease would not have occurred if the pathogen had not been present on the raw product in the first place." *Id.*

In addition to the HACCP rules, the USDA has also addressed the dangers of E. coli O157:H7 in a 1999 policy statement—the statement on which petitioner places almost total reliance in this case—indicating that since 1994 it had generally regarded, and would continue to regard, "non-intact" cuts of meat as "adulterated" if they were contaminated with E. coli O157:H7. *See* 64 Fed. Reg. 2803.[3] The USDA also indicated that, with one narrow exception, it regards "intact cuts" as adulterated when they are contaminated with E. coli O157:H7. *See* 64 Fed. Reg. 2803 ("[t]he public health risk presented by beef products contaminated with E. coli O157:H7 is not limited . . . to raw ground beef products"). In setting forth this policy, the Agency explicitly recognized that, while contamination with E. coli O157:H7 takes place on the surface of intact cuts (and thus is more easily destroyed by cooking), many intact cuts undergo further processing before cooking, either at separate processing plants or at retail establishments. *Id.* That additional processing may include certain methods of tenderizing, as

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[3] The USDA, acting through the FSIS, stated that "[t]his notice explains the Agency's policy governing beef products that contain the pathogen Escherichia coli O157:H7 (E. coli O157:H7)." 64 Fed. Reg. 2803. We thus use the terminology "policy statement" to refer to the notice. While petitioner refers to the statement as an "interpretive rule," the distinction between the two terms is immaterial in this context. *See United States v. Mead Corp.*, 533 U.S. 218, 234 (2001) (noting that "interpretations contained in policy statements . . . are beyond the *Chevron* pale") (internal quotation marks omitted). *See* pages 16-17 *infra* (discussing various deference standards).

well as the conversion of leftover trimmings into ground beef products. *See* 64 Fed. Reg. 2804. In those situations, "[p]athogens may be introduced below the surface of these products as a result of the processes by which they are made." *Id.* The Agency thus stated that it views contaminated intact cuts in the same manner as non-intact cuts—that is, it regards them as "adulterated"—unless they "are to be distributed for consumption as intact cuts." *Id.*[4]

B. The Proceedings Below.

These consolidated cases were filed by, or on behalf of, persons who contracted E. coli O157:H7 food poisoning in July 2000, after eating at a Sizzler Restaurant in Milwaukee, Wisconsin. A three-year old girl, Brianna Kriefall, died as a result of the E. coli poisoning.[5]

The suits named several defendants, including respondent Sizzler and petitioner Excel. The claims against petitioner, all grounded in state law, included claims based on negligence, negligence per se for violating provisions of state law, and strict liability. *See, e.g.*, Kriefall Plaintiffs' Second Amended Complaint ¶¶ 100-139; Lesak Plaintiffs' First Amended Complaint ¶¶ 4.1-6.9. Plaintiffs also asserted various warranty claims against petitioner, including breach of express warranty, contending that they were third party

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[4] There are open questions about the extent to which the USDA has implemented the policy statement. *See* 65 Fed. Reg. 6881, 6886 (Feb. 11, 2000) (noting that the Agency "delayed implementation of the policy discussed in the January 19, 1999 policy statement because it was waiting for the results of the risk assessment for E. coli O157:H7 in ground beef and needed time to consider comments received concerning the policy"). Nonetheless, for purposes of this brief, we will assume that the policy has been implemented.

[5] Petitioner sought to remove the cases to federal court, basing its argument on the pervasiveness of the federal regulatory program. The federal district court rejected this argument and remanded the cases to state court.

beneficiaries of those warranties. *See, e.g.*, Kriefall Plaintiffs' Second Amended Complaint ¶¶ 140-181; Lesak Plaintiffs' First Amended Complaint ¶¶ 7.1-7.4.

Respondent Sizzler filed a cross-claim against petitioner. The cross-claim alleged that, through a contractual "continuing guarantee," petitioner had agreed to provide Sizzler with beef products that met all federal and state standards. *See, e.g.*, Sizzler USA Franchise, Inc. Cross-Claim ¶¶ 10, 12, 14, 16. In addition, it alleged that petitioner had undertaken obligations, and made affirmative representations, with respect to the quality and safety of its products. *See, e.g.*, *id.* ¶¶ 13-17. The cross-claim asserted causes of action based on breach of contract, fraud in the inducement, and breach of express and implied warranties. *See id.* ¶¶ 51-86.

The circuit court granted summary judgment for petitioner, finding that federal law preempted the state-law claims. Noting that, according to the 1999 USDA policy statement, "'intact products that are to be distributed for consumption as intact cuts are not deemed adulterated,'" Pet. App. 49a (quoting 64 Fed. Reg. 2804), the court held that the state-law tort claims fell within the terms of the Act's express preemption clause, 21 U.S.C. § 678, which bars States from imposing "[r]equirements . . . with respect to premises, facilities and operations of any establishment . . . which are in addition to, or different than those made under this chapter . . . . " *Id.* (The preemption clause is set forth in full at Pet. App. 60a.) Although respondents had argued, as a matter of fact, that the products sold by petitioner were *not* "intact products that are to be distributed for consumption as intact cuts," the circuit court did not resolve, or even acknowledge, this factual dispute. Nor did the court discuss whether state-law tort suits imposed "requirements" within the meaning of the express preemption clause, or, if they did so, whether those "requirements" were properly considered to be "with respect to premises, facilities and operations" of an inspected

establishment. Rather, after reviewing the extent of federal regulation under the Act, the court simply concluded that "[t]he federal regulatory scheme is so long-standing and so comprehensive that . . . it preempts any state laws to the contrary." Pet. App. 50a.

The circuit court also granted summary judgment on the contractual and warranty claims. *See* Pet. App. 50a. As to plaintiffs' claims, the court declared that "warranty claims require privity, and the plaintiffs here were not in privity with [petitioner] in the 2000 sale." *Id.* More generally, the court found that a "merger clause" in a January 2000 agreement between petitioner and Sysco Services—which had purchased the contaminated meat in question from petitioner and then resold it—precluded reliance on the terms of earlier agreements containing warranties and representations made by petitioner. It thus held that, while plaintiffs might pursue their claims against other defendants, "they may not sue Excel." *Id.*

The court of appeals reversed. With respect to the express preemption issue, the court concluded that the USDA policy statement cited by the circuit court was not dispositive in this case for two independent reasons. First, it observed that the policy statement regarded as not adulterated only intact cuts "that are to be distributed for consumption as intact cuts," and that the HACCP plan adopted by petitioner expressly indicated that "intact cuts of beef [at petitioner's plant] were 'intended to be sold raw . . . for further processing at retail.'" Pet. App. 18a (quoting the HACCP plan). Second, it concluded that the USDA policy statement—which necessarily viewed some intact cuts contaminated with E. coli O157:H7 as not potentially "injurious to health"—was inconsistent with the language and purpose of the Act. *See* Pet. App. 19a; 21 U.S.C. § 601(m)(1), (4). The court thus held that "the statutory definition controls." *Id.*

The court of appeals also found that the state-law claims were compatible with the scheme of federal regulation as a whole. In so doing, the court of appeals emphasized the numerous steps that the USDA had taken to eliminate E. coli O157:H7 in meat processing facilities. The court observed that, as the USDA had shifted its focus from reliance on its own monitoring activities to reliance on HACCP plans implemented and enforced by the establishments themselves, *see* Pet. App. 21a, it had taken a rigorous stance with respect to fecal contamination, *see* Pet. App. 24a-26a, imposing a policy of "zero tolerance." Pet. App. 26a. Likewise, it noted declarations by the USDA that the Agency "'considers an acceptable reduction for E. coli O157:H7 to be a reduction to an undetectable level.'" *Id.* (quoting 67 Fed. Reg. 62,329). Given the USDA objective of eliminating E. coli O157:H7 contamination during the slaughtering process, the court of appeals reasoned that state-law suits based on illnesses caused by contaminated meat would reinforce, not contradict, the provisions of federal law.[6]

The Supreme Court of Wisconsin denied a petition for review. Pet. App. 44a.

ARGUMENT

This case does not warrant further review. To begin with, the state court judgment is not final. *See* 28 U.S.C. § 1257(a). Although petitioner argues that this Court may exercise

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[6] The court pointed out that the USDA itself had recognized "the significant limitations of the 'organoleptic examination by inspectors,'" Pet. App. 32a (quoting 61 Fed. Reg. 38,838), especially with respect to organisms like E. coli O157:H7. It observed that "seven-foot-long carcasses arrive at the fabrication area after whizzing by the Service inspection station at the rate of one side every six seconds." *Id.* And, while those carcasses are later split into "some 8,000 intact cuts of beef weighing approximately two to four or three to five pounds each," *id.*, "[f]ederal inspectors do not inspect each one of these smaller cuts of beef." *Id.*

jurisdiction because reversal of the judgment would be "'preclusive of any further litigation,'" Pet. 16 n.4 (quoting *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 482 (1975)), that argument is clearly incorrect. For one thing, the Wisconsin Court of Appeals found that petitioner—as a distributor of meat cuts that may receive "further processing," rather than cuts sold only for "consumption as intact cuts" (64 Fed. Reg. 2804)—would not benefit from the very USDA policy statement that it seeks to rely on, regardless of whether the policy statement received judicial deference or not. Furthermore, the issue of how much (if any) deference is due to the Agency policy statement regarding E. coli O157:H7—the sole issue raised by the Question Presented (Pet. i)—is just one of many issues that would have to be resolved in petitioner's favor before it would be entitled to termination of the lawsuits against it. The court of appeals, in the opinion below, expressly left those other issues open.

Even leaving prematurity aside, the decision is correct and of little general importance. Because the policy statement issued by the USDA is concededly not entitled to *Chevron* deference, *see Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the only question is whether it is entitled to *Skidmore* deference, *see Skidmore v. Swift & Co.*, 323 U.S. 134 (1944): that is, in specific terms, whether the Agency has persuasively established that it is acceptable to regard certain cuts of meat contaminated with E. coli O157:H7 as not potentially "injurious to health." *See United States v. Mead Corp.*, 533 U.S. 218, 235 (2001) (deference given to agency judgments under *Skidmore* in accordance with their "power to persuade"). Looking to the language and purpose of the statute, and to the overall USDA objective of eliminating E. coli O157:H7 from meat processing facilities, the court of appeals reasonably concluded that a policy of regarding some E. coli O157:H7 contaminated meat as harmless was not persuasive enough to warrant deference. Furthermore, the decision below established no ground-

breaking principle of law, but merely determined that one particular USDA policy statement, applying to a single type of bacterium in a single situation, would not be regarded as definitive in a state-law tort suit. Nothing in that decision calls for review by this Court.

I. THE JUDGMENT BELOW IS NOT FINAL.

The express terms of 28 U.S.C. § 1257(a) establish that this Court has jurisdiction to review only "final judgments or decrees" from state courts. *See Jefferson v. City of Tarrant*, 522 U.S. 75 (1997). Although this requirement does not mean that state-court proceedings must always be terminated in their entirety, *see Cox Broadcasting*, 420 U.S. at 477, the Court has agreed to review issues in the midst of ongoing state cases in only a few narrow categories of cases. Petitioner tries to fit within one of those categories here, arguing in two-step fashion, *first*, that proper deference to the USDA policy statement would mean that "the state-law cause of action against Excel would be preempted," Pet. 16 n.4, and, *second*, that, as a result, "'reversal of the state court on the federal issue would be preclusive of any further litigation.'" *Id.* (quoting *Cox Broadcasting*, 420 U.S. at 482-83).[7] But this chain of reasoning is demonstrably wrong. For

[7] This Court in *Cox* noted that it had reviewed judgments from state courts, *inter alia*, in "situations where the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court, and where *reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action* rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come. In these circumstances, if a refusal immediately to review the state court decision might seriously erode federal policy, the Court has entertained and decided the federal issue, which itself has been finally determined by the state courts for purposes of the state litigation." 420 U.S. at 482-83 (emphasis added).

a number of reasons, "a reversal . . . on the federal issue"—*i.e.*, the extent of deference owed to the USDA policy statement—would not come close to being "preclusive of any further litigation" against petitioner.

A. The first problem faced by petitioner is that a reversal, rather than precluding all litigation against it, would not help it at all. The reason is simple: petitioner has not established that its product falls within the narrow category of meat products that may be deemed not adulterated, even though they are contaminated with E. coli O157:H7. Thus, while petitioner describes the USDA E. coli O157:H7 policy statement as though it permitted the sale of all intact cuts, *see* Pet. 2, 10, 20, that characterization is notably incomplete: in fact, the policy statement makes an important distinction *within* the category of intact cuts, explicitly treating contaminated intact cuts as "adulterated" if they may be subject to further processing. *See* 64 Fed. Reg. 2804. In addressing petitioner's efforts to rely on the USDA policy statement, the court of appeals specifically recognized the difference between various categories of intact cuts, observing that the possible use of a particular meat product was necessarily of critical significance in determining whether it was "adulterated" under that standard. *See* Pet. App. 18a. Then, referring to petitioner's HACCP plan, the court pointedly observed that "its intact cuts of beef were 'intended to be sold raw . . . *for further processing at retail*.'" Pet. App. 18a (emphasis added).

Petitioner candidly acknowledges this defect in its position, conceding that the court of appeals "intimated that the meat involved in this case therefore should be classified as non-intact." Pet. 14 n.3. It then goes on to argue, however, that the court of appeals was mistaken, claiming that "the meat products produced by Excel that ended up at the E&B Sizzler restaurant were intact cuts of sirloin." *Id.* But that assertion, even if correct as stated, is beside the point: the issue is not

whether the products received at Sizzler "were intact cuts of sirloin," but whether the products were necessarily *to be consumed as intact cuts* without additional processing. On that question, as respondents argued below, a proper evidentiary record would show full awareness by petitioner that the type of cuts at issue here (so-called "tri-tips," weighing from three to five pounds) would routinely be subject to further processing at other facilities or at retail establishments (like Sizzler), including mechanical tenderizing processes that can cause E. coli O157:H7 to penetrate to the interior of the meat. *See*, *e.g.*, C.A. Brief of Lesak Plaintiffs-Appellants 23-32. It thus was entirely appropriate for the court of appeals to decide that, according to the terms of its own HACCP plan, petitioner was in no position to use the USDA policy statement to avoid liability.

In any event, with respect to petitioner's factual contentions, it seems obvious that this Court is not the forum in which to resolve whether petitioner did, or did not, distribute meat that might receive further processing. The case is before the Court on reversal of a summary judgment, and these sorts of factual questions have yet to receive a full airing. Whatever the ultimate outcome, it is clear under Wisconsin law that "[d]oubts as to the existence of a genuine issue of material fact should be resolved against the party moving for summary judgment." *Grams v. Boss*, 294 N.W.2d 473, 477 (Wisc. 1980); *see also Lambrecht v. Estate of Kaczmarczyk*, 623 N.W.2d 751, 759 (Wisc. 2001) (same). Under that standard, the court of appeals rightly treated petitioner as a distributor of intact cuts "for further processing at retail," not as a distributor of cuts "for consumption as intact cuts." As such, petitioner would not be entitled to judgment in its favor, regardless of the deference given to the USDA policy statement.

B. A reversal would not preclude further litigation against petitioner for other reasons as well. Even if petitioner were to

prevail on the "deference" issue that it raises in the Question Presented, and even if petitioner would actually benefit from that deference, it still would have taken only the first of several required steps towards obtaining dismissal of respondents' claims. As the court of appeals made clear below, several other important issues remain open, if necessary, in further proceedings.

The first of those outstanding issues is whether the state-law claims at issue would constitute "requirements" within the meaning of the Act's express preemption clause. *See* 21 U.S.C. § 678 ("[r]equirements within the scope of this chapter with respect to premises, facilities and operations of any [inspected] establishment . . . which are in addition to, or different than those made under this chapter may not be imposed by any State . . . .") Although this Court has indicated that state-law claims may constitute "requirements" under the language of a particular preemption provision, *see Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality opinion); *id.* at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part), it is hardly self-evident that they always do so, or that they would do so here. Indeed, the language of the Federal Meat Inspection Act preemption clause, read in context, would appear more naturally to refer to formal state administrative requirements, rather than to common law remedial actions arising out of injuries suffered as a result of contaminated products. Moreover, it is noteworthy that the Act contains no right of action for consumers killed or made ill by contaminated meat products, even though Congress was surely aware that, notwithstanding the USDA inspection process, hundreds of people are exposed each year to unsafe meat. To insist upon preemption of all state claims arising out of "approved" meat products thus would require an assumption that Congress meant to bar States from affording relief to their citizens in an area (public health) that is of traditional state concern—an assumption that is contrary to the usual understanding of what

Congress intends. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress'") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("common-law claims . . . necessarily perform an important remedial role in compensating accident victims"). The court of appeals, while noting the difficulties raised by this issue, expressly declared that it was not resolving it. *See* Pet. App. 6a n.3.

There are also open questions regarding whether the various claims in this case, assuming that they impose "requirements" at all, would do so "with respect to premises, facilities and operations" of an inspected establishment and would be "in addition to, or different than" the relevant federal requirements. Again, the court of appeals expressly reserved decision on the proper application of that language. *See* Pet. App. 8a n.3. The term "with respect to" has no defined meaning in this context, and the phrase may reasonably be read to refer to specific targeted requirements, rather than to more general tort requirements (*e.g.*, negligence or strict liability) that happen to have an incidental effect on meat processing operations. *See generally California Div. of Labor Standards Enforcement v. Dillingham Constr. N.A., Inc.*, 519 U.S. 316 (1997). Moreover, as we discuss later, the USDA has established a policy of "zero tolerance" with respect to fecal contamination in inspected establishments, and it has further declared that E. coli O157:H7 should be reduced to "undetectable levels." *See* pages 20-21 *infra*. The claims here, which result from meat contaminated with E. coli O157:H7, are entirely consistent with—indeed, affirmatively reinforce—those objectives.

Finally, there are significant remaining questions about whether petitioner has undertaken voluntary contractual and warranty obligations that are enforceable without regard to any preemption defense. Given its disposition of the case, the court of appeals once again found no need to address those issues. *See* Pet. App. 36a n.8. But it is well-recognized that, preemption law notwithstanding, companies may properly be held accountable for failing to comply with contractual or other representations. *See American Airlines, Inc. v. Wolens*, 513 U.S. 219, 232-33 (1995); *Cipollone*, *supra*, 505 U.S. at 525-27 (plurality opinion). Although the Wisconsin circuit court held that respondents could not rely on petitioner's voluntary undertakings because of a lack of privity, and because of a merger clause in a subsequent contract, there are strong reasons to think that the court misread both the terms of the relevant contracts and Wisconsin law. *See* C.A. Brief of Defendant-Third Party Sizzler USA Franchise, Inc. 18-30. Hence, petitioner faces liability on those grounds, regardless of its success (or lack of it) in establishing preemption of other claims.

The final judgment requirement is "not one of those technicalities to be easily scorned." *Radio Station WOW, Inc. v. Johnson*, 326 U.S. 120, 124 (1945). Rather, "[i]t is an important factor in the smooth working of our federal system." *Id. See also Costarelli v. Massachusetts*, 421 U.S. 193, 196 (1975) (rule "prevent[s] our interference with state proceedings when the underlying dispute may be otherwise resolved"). As this Court has said: "The finality requirement of 28 U.S.C. § 1257 . . . serves several ends: (1) it avoids piecemeal review of state court decisions; (2) it avoids giving advisory opinions in cases where there may be no real 'case' or 'controversy' in the sense of Art. III; (3) it limits review of state court determinations of federal constitutional issues to leave at a minimum federal intrusion in state affairs." *North Dakota State Bd. of Pharmacy v. Snyder's Drug Stores, Inc.*,

414 U.S. 156, 159 (1973). Those principles are fully applicable here. The petition is premature.

II. THE PETITION DOES NOT, IN ANY EVENT, WARRANT REVIEW.

Quite apart from its procedural faults, the petition raises no issues meriting review by this Court. Although petitioner vigorously argues that the USDA E. coli O157:H7 policy statement is entitled to deference, and that the court of appeals impermissibly failed to give it "any weight," *see, e.g.*, Pet. i, 16, that narrow question—involving one out of thousands of federal rules and policy statements—is of no general importance. And, in any event, the court below was right to conclude that, in light of the governing statute and the regulatory scheme as a whole, there was no reason to accord deference to one questionable aspect of this particular USDA policy statement.

A. At the outset, we note that petitioner does not make any argument that the Wisconsin court was required to give *Chevron*-type deference to the USDA policy statement. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). This Court has held that the more substantial *Chevron* deference is generally reserved for rules adopted after notice-and-comment rulemaking. *See United States v. Mead Corp.*, 533 U.S. 218, 229-30 (2001). Although the Court has recognized a few additional situations in which *Chevron* deference is appropriate, *see id.* at 231, nothing in the actions of the USDA with respect to the E. coli O157:H7 policy statement—even assuming that it has actually been implemented, *see* note 4 *supra*—brings them within that limited class. Consequently, the court of appeals was under no obligation to defer to the Agency pursuant to the standards of that doctrine.

The policy here thus would be entitled to, at most, *Skidmore*-type deference. *See Skidmore v. Swift & Co.*, 323

U.S. 134 (1944); *see also Mead*, 533 U.S. at 234-35; *Christensen v. Harris County*, 529 U.S. 576, 587 (2000). As this Court has indicated, that kind of deference acknowledges that government agencies may develop levels of experience and knowledge in the course of administering federal statutes. *See Mead*, 533 U.S. at 234-35. This recognition does not mean, however, that courts must follow agency interpretations of federal law. Rather, under the standards of *Skidmore* deference, the agency view is to be given respect to the extent of, but only to the extent of, its "power to persuade." *See Mead*, 533 U.S. at 235; *Christensen*, 529 U.S. at 587.

Nothing in the decision below is contrary to these principles. All that the court of appeals did—and what, under *Skidmore*, it was fully entitled to do—was to determine that, insofar as the applicable USDA policy statement posited that certain intact cuts contaminated with E. coli O157:H7 were not potentially "injurious to health," it lacked the "power to persuade." The court noted that the relevant statutory language defined adulterated products in terms of whether poisonous substances or insanitary conditions "may render" meat products "injurious to health," *see, e.g.*, 21 U.S.C. § 601(m)(1), (4), and it further noted that the overriding purpose of the statute was to safeguard public health against the harm posed by contaminants like E. coli O157:H7. *See* Pet. App. 10a; *see also* 21 U.S.C. § 602 ("[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged"). Given the Act's language and purpose, and the USDA's own explanations regarding the severe dangers arising from E. coli O157:H7, the court below simply concluded that the presence of E. coli O157:H7 on meat products posed the kind of threat to public

health targeted by the statute, at least under the circumstances present here.[8]

This reasoning makes sense for several reasons. In the first place, there is no doubt that E. coli O157:H7 is a "poisonous or deleterious substance," *see* 21 U.S.C. § 601(m)(1), and that it may occur "under insanitary conditions." *See* 21 U.S.C. § 601(m)(4). Moreover, E. coli O157:H7 is indisputably capable of causing serious harm, even in small quantities. The USDA itself has stated: "Some pathogens, such as E. coli O157:H7 are so virulent that a small number of organisms can pose a significant hazard," 61 Fed. Reg. 38,835, concluding that "any amount of E. coli O157:H7 will adulterate a meat or poultry product." *Id.*; *see also* 65 Fed. Reg. 6883 ("E. coli O157:H7 is a particularly virulent pathogen").[9]

It is also clear that "[t]he public health risk presented by beef products contaminated with E. coli O157:H7 is not

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[8] We note that there might be grounds for claiming more than *Skidmore* deference to the views of the Secretary under 21 U.S.C. § 601 (m)(2), which defines one kind of adulterated product and explicitly leaves the question whether a substance makes a product "unfit for human food" up to the "judgment of the Secretary." *See id.* As the court of appeals pointed out, however, that language is absent from the other definitional provisions of Section 601(m). *See* Pet. App. 19a.

[9] Although petitioner compares E. coli O157:H7 to other forms of bacteria like Salmonella and trichinae spiralis, *see* Pet. 24, the question whether various pathogens may be injurious to health does not lend itself to a one-size-fits-all answer. For example, the USDA has declared that the threat posed by E. coli O157:H7 is greater than the threat posed by other bacteria that are harmful only in far larger quantities. *See, e.g.*, 61 Fed. Reg. 38,835 (noting that, in contrast to E. coli O157:H7, salmonella "must multiply to relatively large numbers to cause illness"). Thus, whether a particular product can safely be sold, despite the presence of bacteria, will necessarily depend on both the nature of the product and the particular bacterium at issue. The decision in this case involves only E. coli O157:H7.

limited . . . to raw ground beef products." 64 Fed. Reg. 2803. As the USDA policy statement recognizes, intact cuts commonly are subjected to further processing, which can cause the E. coli O157:H7 bacteria to penetrate below the surface of the meat. Thus, if meat contaminated with E. coli O157:H7 could ever sensibly be regarded as safe for distribution to consumers, it would have to be under circumstances where there was sufficient assurance, at the time of inspection, that the contaminated cuts would be consumed without further treatment. *See* 64 Fed. Reg. 2803 (noting importance of "adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed"). There is nothing even approaching that assurance here. To the contrary, as the court of appeals noted, it was generally understood that the intact products at petitioner's facility, like those at many other meat processing facilities, were likely to receive further processing. *See* Pet. App. 18a (discussing petitioner's HACCP plan). Indeed, an Excel official testified at his deposition that Excel plant employees (and, presumably, USDA inspectors) typically do not know the intended use of the carcasses presented for examination and approval. *See* C.A. Lesak Brief 30-31 (quoting Klingaman Aff., Ex. E., Goltry Dep. at 322-24). Under those circumstances, it is simply not possible to predict, with any reliable level of confidence, that a particular carcass or large cut of meat contaminated with E. coli O157:H7 would not be potentially "injurious to health."

Petitioner suggests, however, that the words "may render it injurious to health" should be given a narrow reading, in order to exclude highly speculative or remote risks arising from commonly-occurring bacteria. *See* Pet. 21, 24. But the risks here were not remote. The court of appeals had ample evidence—much of it contained in declarations by the USDA itself—from which to conclude that the dangers posed by E. coli O157:H7 were neither fanciful nor inconsequential, even with respect to intact cuts. Thus, while petitioner is doubtless

correct that some levels of risk may be too slight to fall within the statutory terms, the presence of E. coli O157:H7 gives rise to significantly more serious concerns.[10]

It is also important to recognize that, under the USDA regulatory approach, meat processors cannot simply assume that later handling will eradicate the risk posed by highly dangerous pathogens like E. coli O157:H7. Thus, while petitioner seeks to rely on the fact that "the bacteria are killed by ordinary cooking," Pet. 20, the Agency has emphasized the importance of eliminating potential hazards *before* harmful products are distributed to the public. *See* Pet. App. 27a (discussing USDA approach). The USDA thus has noted that the "first, and critical step" leading to foodborne illness is "the introduction of a pathogen into or onto the raw product," 61 Fed. Reg. 38,966, a step that only takes place as a result of improper slaughtering and processing. Although it is certainly true that "ordinary cooking" may reduce the chances of resulting illness, the USDA found no justification for processors to ignore the problem at its source, stating that "disease would not have occurred if the pathogen had not been present on the raw product in the first place." *Id.*

The objective of preventing E. coli O157:H7 contamination at the slaughterhouse is directly reflected in the USDA policies regarding meat processors' HACCP plans. The USDA has stated that "preventing and removing fecal contamination and associated bacteria are vital responsibili-

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[10] In *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914), this Court indicated that similar language in a federal statute ("may be injurious to health") is properly construed to take account of potential harm even to unusually susceptible consumers. Noting that flour (the product there at issue) "may be consumed . . . by the old and the young, the well and the sick," *id.* at 411, the Court in *Lexington Mill* concluded that "if any flour, because of any added poisonous or other deleterious ingredient, *may possibly injure* the health of any of these, it shall come within the ban of the statute." *Id.* (emphasis added).

ties of slaughter establishments," 61 Fed. Reg. 38,837, which establishments—rather than the USDA—now bear the primary responsibility for meat safety. *See* page 3 *supra*. Importantly, given the suggestions by petitioner that harmful bacteria are an inevitable aspect of dealing with meat products, Pet. 21, 24, the Agency has made a point of saying that "such contamination is largely preventable." *Id.* Thus, the Agency has indicated that, in HACCP plans, it will require "a slaughter establishment's adherence to zero tolerance for fecal contamination." 61 Fed. Reg. 38,850. Taking a similarly stringent view with respect to E. coli O157:H7 itself, the Agency has said that it "considers an acceptable reduction for E. coli O157:H7 to be a reduction to an undetectable level." 67 Fed. Reg. 62,329.

In light of this broad statutory and regulatory background, therefore, the court of appeals was fully justified in concluding that meat contaminated with E. coli O157:H7 was, in a very real sense, potentially "injurious to health," within the meaning of 21 U.S.C. § 601(m). Not only does the USDA acknowledge the dangers posed by even a small amount of E. coli O157:H7, it further recognizes that meat processors cannot always depend on later handling to eliminate the danger. It follows, therefore, that the distribution of meat products contaminated with E. coli O157:H7—whether they are "intact cuts" or not—can lead to just the sort of harm to unsuspecting consumers that occurred here. To the extent that parts of the USDA "adulteration" policy statement can be taken to indicate otherwise, it lacks persuasive force and need not be given judicial deference.

B. The decision below is also of limited importance. The Wisconsin Court of Appeals announced no novel principles regarding whether, and when, to give deference to federal administrative agencies. Rather, it simply declined to apply one aspect of one policy statement addressing one particular hazardous contaminant, solely for the purpose of adjudicating

certain state-law tort claims. While the decision declines to follow petitioner's view of the USDA policy statement with respect to those particular claims, nothing in the decision bars the Agency—which, after all, was not a party to these proceedings—from deciding for itself how to carry out its discretionary enforcement duties. Nor does it take any position with regard to meat products contaminated with pathogens other than E. coli O157:H7.

Although petitioner argues that the decision below will create widespread uncertainty about the obligations of meat processing facilities, Pet. 22-26, this concern is overstated. As noted, the USDA already requires facilities to adopt stringent standards in order to prevent fecal contamination, seeking to eradicate the incidence of E. coli O157:H7. *See* pages 2-4, 21 *supra*. Insofar as those objectives are in question, therefore, the state court view of E. coli O157:H7 as a potentially dangerous substance, even on most intact cuts, poses no obstacle to the federal program. If anything, the possibility of state liability actions provides a complementary incentive to rid processing facilities of the threat posed by fecal contamination.

To be sure, the ruling below does raise the prospect that slaughterhouses and processors may face liability for injuries or deaths caused by the sale of contaminated meat, even if that meat has managed to pass through the federal inspection process. But, as the court of appeals noted, petitioner cannot expect that federal inspection will result in detection and disapproval of all contaminated meat, given that inspectors (relatively few in number, to begin with) are exposed to 350-pound carcasses for approximately six seconds apiece. *See* Pet. App. 32a. Indeed, petitioner has workers known as "defect trimmers" that are assigned to remove fecal contamination *after* the carcasses have received "approval" at the slaughtering stage. Furthermore, it is significant that the USDA conducts random testing and evaluation at *retail*

establishments, necessarily reflecting its own understanding that pre-distribution inspection is not a foolproof system.[11] It is thus entirely appropriate to preserve the opportunity for injured consumers to obtain relief from processors that sell contaminated meat products.

Petitioner also asserts that the decision below raises the prospect of disuniformity, contrary to congressional intent. Pet. 15, 22, 26. But this argument, familiar to most preemption cases, is largely out of place here. Unlike areas like labeling and packaging—where the need for uniformity is typically at its highest (*see, e.g., Jones v. Rath Packing Co.*, 430 U.S. 519 (1977))—the operations of each processing facility are conducted according to its own HACCP plan, which naturally will vary according to the particular needs and concerns of the individual facility. *See* Pet. App. 31a-32a. At the same time, of course, all HACCP plans share the common goal of eliminating fecal contamination and E. coli O157:H7. Again, in that regard, the decision below helps to promote uniformity, not to undermine it.

C. Finally, petitioner says that the decision below is in conflict with *Boulahanis v. Prevo's Family Market, Inc.*, 583 N.W.2d 509 (Mich. 1998), *cert. denied*, 530 U.S. 1203 (2000), and several decades-old cases from federal courts of appeals. The *Boulahanis* decision, however, involved a sale of meat prior to the time that the USDA regarded E. coli O157:H7 as a threat to public health. Thus, unlike the present case, there was no regulatory history of USDA efforts to eradicate E. coli O157:H7 in processing plants, reinforced by

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[11] The lack of absolute certainty with respect to inspected meat products is illustrated by the fact that, prior to 1994, the USDA did not specifically include E. coli O157:H7 in its list of adulterants, in spite of its highly virulent nature. During that earlier period, therefore, USDA inspectors would have "approved" even ground beef contaminated with E. coli O157:H7, although the Agency now acknowledges that contaminated ground beef plainly may be "injurious to health."

Agency recognition that it was necessary to stop E. coli O157:H7 at the source rather than to depend upon later handling to neutralize already-present contamination. Without that background, the Michigan court had no sufficient reason to question the implicit USDA determination—which proved mistaken, of course, and has since been abandoned—that the sale of meat (there, ground meat) contaminated with E. coli O157:H7 was not potentially "injurious to health." Its decision, therefore, does not conflict with the decision below, which takes account of a very different regulatory record.

There is also no conflict with the cited federal cases. *See Grocery Manufacturers of Am., Inc. v. Gerace*, 755 F.2d 993 (2d Cir. 1985); *National Pork Producers Council v. Bergland*, 631 F.2d 1353 (8th Cir. 1980); *Public Citizen v. Foreman*, 631 F.2d 969 (D.C. Cir. 1980). In the first place, each of the regulations at issue in those cases was promulgated after a far more formal and extensive process. *See Gerace*, 755 F.2d at 1001 (citing *Federation of Homemakers v. Schmidt*, 539 F.2d 740 (D.C. Cir. 1976), which had upheld an underlying FDA rule promulgated after notice and comment, *see id.* at 742); *Bergland*, 631 F.2d at 1357; *Foreman*, 631 F.2d at 973. Those cases thus raised questions of *Chevron*-type deference, *see Mead*, 533 U.S. at 229-30, a degree of deference that petitioner does not, and could not, ask for here. Moreover, not surprisingly, none of those federal courts held, or had any reason to hold, that USDA policy statements (or interpretive rules, *see* note 3 *supra*) must be treated as authoritative even if they lack the "power to persuade," and they certainly did not indicate that deference must be given to pronouncements that are inconsistent with either the import of the governing statute or other pronouncements of the USDA itself. The claimed conflict is thus entirely imaginary.

In short, the petition is too little, too soon. Further review is not warranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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